Food and Drug Administration

Transmissible Spongiform Encephalopathies Advisory Committee

February 12, 2004

Issue Summary for Topic #4 F, "Update on the Washington State BSE Case"

Issue: Impact on FDA-regulated Foods, including Dietary Supplements, and Cosmetics

Background:

FDA has jurisdiction over most food products, including those that contain a relatively small proportion of meat (exempted under the Federal Meat Inspection Act). Many of the foods, including dietary supplements, food additives, and food ingredients, and cosmetics regulated by FDA contain beef or components of beef. Examples of the bovine-origin products regulated by FDA are soups and stocks, beef flavors and extracts, gelatin, collagen, amino acids, and foods that contain small amounts of beef, such as pizza, multi-component frozen meals, and entrees. Many cosmetics contain tallow or tallow derivatives, gelatin, collagen, and other bovine components. Dietary supplements are often enclosed in gelatin capsules and may be composed of a variety of bovine tissues.

Foods, including dietary supplements, food additives, and food ingredients may be formulated from any ingredient that is safe and wholesome, unless specifically prohibited by regulation. Since 1992, the agency has strongly recommended that firms manufacturing or importing foods that might contain bovine tissues, including extracts or substances derived from these tissues, take whatever steps are necessary to reduce the potential risk of human exposure to or transmission of the infectious agent that causes BSE. Since 1992, FDA has advised dietary supplement manufacturers and distributors that they should take steps to ensure that no dietary supplement ingredients come from cattle born, raised or slaughtered in any country known to have BSE or that has inadequate controls to detect and control it.

Except for color additives and those ingredients prohibited or restricted by regulation, a manufacturer may essentially use any ingredient in the formulation of a cosmetic product provided the product is safe, properly labeled, and not adulterated by use of the ingredient. As is true for foods, including dietary supplements, since 1994, we have strongly recommended that firms manufacturing or importing cosmetic products that contain bovine tissues, including extracts or substances derived from these tissues, take

whatever steps are necessary to reduce the potential risk of human exposure to or transmission of the infectious agent that causes BSE.

Gelatin produced from bovine hides and bones is used in foods, including dietary supplements, cosmetics, and many other FDA-regulated products. In 1997, to reduce the risk of BSE transmission, the agency published guidance on production of gelatin for oral consumption that

recommended removal of the skull, spine and spinal cord and made recommendations on sourcing of bones and hides. During the July 2003 TSEAC meeting, evidence on the effectiveness of gelatin processing was presented to the committee. We are considering the need to revise the guidance in view of the pending issuance of the BSE regulation recently announced by FDA. If the gelatin guidance is still necessary, we will revise it taking into consideration the committee's comments and the provisions of the regulation. The agency also recently received a petition to modify the guidance. If the gelatin guidance is revised, it will be presented at a TSEAC meeting later in 2004.

The identification of the first case of BSE in the United States., even though the animal was imported from Canada, triggered emergency response reactions by USDA and FDA to retrieve products of the slaughter that went to edible and inedible rendering. USDA published regulations that prohibit the inclusion in human food of downer cattle, SRMs from cattle 30 months of age or older, and the product Mechanically Separated Beef, and established new standards for Advanced Meat Recovery meat to limit central nervous system tissue in the product. The general flow of bovine-origin materials into FDA-regulated foods, dietary supplements, and cosmetics influences the degree of BSE risk to consumers in the United States, and is under agency review.

CURRENT

On January 26, 2004, FDA announced that it intends to publish a regulation that bans in human foods, including dietary supplements, and cosmetics:

- ?? Use of non-ambulatory disabled animals and animals that die before being presented for slaughter
- ?? Specified Risk Materials,
- ?? Mechanically Separated (Beef), and
- ?? Tissue from animals that are inspected and not passed for human consumption

This will be an interim final regulation, open to public comment, that essentially parallels actions taken by USDA in their interim final rules published January 12, 2004.